

IN THE CLAIMS

1 Claim 1 (currently amended): A process for analyzing a medical condition of a user
2 comprising the following steps:

- 3 a) reading at least one signal from a said user;
- 4 b) transforming said at least one signal into at least one digital signal;
- 5 c) extracting a plurality of parameters from said at least one digital signal;
- 6 d) analyzing said plurality of parameters and comparing said plurality of
7 parameters to a range in a set of a plurality of preset parameters;
- 8 e) determining whether a said user has an abnormal medical condition by
9 determining whether said plurality of parameters fall outside of said range in said
10 plurality of preset parameters;

11 wherein said step of determining whether said user has an abnormal
12 medical condition further includes a step of setting said range in said plurality of preset
13 parameters based upon a medical history of said user, an average formed from a plurality
14 of previous users and a normal range of said plurality of parameters; and

- 15 f) determining whether to trigger an alarm warning ~~the~~ said user of his or
16 her medical condition when said at least one of said plurality of parameters ~~fall~~ falls
17 outside of said ~~preset~~ ranges for said plurality of preset parameters.

1 Claim 2 (currently amended): The process as in claim 1, further comprising the step of
2 selecting a particular alarm from a set of a plurality of alarms for the user based upon
3 which of said plurality of parameters fall outside of said range of said plurality of ~~said~~
4 preset parameters.

1 Claim 3 (currently amended): The process as in claim 1, wherein said step of extracting
2 a plurality of parameters includes extracting a plurality of data points from said at least
3 one digital signal and forming at least one QRS ~~wave~~ complex from said plurality of data
4 points.

Claims 4-18 (canceled)

1 Claim 19 (original): The process as in claim 1, further comprising the step of
2 determining whether to send a signal to the user to administer a form of external stimuli.

Claims 20 (canceled)

1 Claim 21 (currently amended): A process for analyzing a medical condition of a user by
2 using a portable information device having a plurality of sensors, at least one ~~digital to~~
3 ~~analog~~ analog to digital converter and at least one transceiver and by using an
4 information processing device having at least one medical information analyzer, at least
5 one data store, at least one parameter analyzer, at least one abnormality identifier and at
6 least one alarm controller wherein the process comprises the following steps:
7 a) reading at least one signal from the plurality of sensors attached to the user;
8 b) transferring said at least one signal from said plurality of sensors into at least
9 one digital signal using the ~~digital to analog~~ analog to digital converter;
10 c) extracting a plurality of parameters from said at least one digital signal using
11 the medical information analyzer;
12 d) analyzing said plurality of parameters and comparing said plurality of
13 parameters to a range in a set of a plurality of preset parameters stored in the data store,
14 by using the parameter analyzer;
15 e) determining whether a the user has an abnormal medical condition by
16 determining whether at least one of said plurality of parameters ~~fall~~ falls outside of said
17 range in said set of said plurality of preset parameters by using the abnormality identifier;
18 and
19 f) determining whether to trigger an alarm warning the user of his or her medical
20 condition when said at least one of said plurality of parameters ~~fall~~ falls outside of said
21 ~~preset ranges~~ range for said set of said plurality of said preset parameters by using the
22 abnormality identifier in conjunction with the alarm controller.

1 Claim 22 (currently amended) The process as in claim 21, further comprising the step
2 of using the alarm controller to select a particular alarm from a set of a plurality of

3 alarms, stored in the at least one data store, for the user based upon which of said
4 plurality of parameters fall outside of said range of said set of said plurality of ~~said~~ preset
5 parameters.

Claim 23 (canceled)

1 Claim 24 (original): The process as in claim 21, further comprising the step of
2 determining whether to send a signal to the user to administer a form of external stimuli.

Claim 25 (canceled)

1 Claim 26 (currently amended) A process for analyzing a medical condition of a user
2 comprising the following steps:

3 reading at least one signal from a user;

4 transferring said at least one signal into at least one digital signal;

5 extracting a plurality of parameters from said at least one digital signal, wherein
6 said plurality of parameters are selected from a group consisting of: pulse rate,
7 intermediate alteration of a pulse rate, R-R interval, premature beats, group of
8 consecutive premature beats, ~~[[an]] atrial/ventricular fibrillation-flutter~~ fibrillation/flutter,
9 ST-segment depression/elevation, T-wave inversion, width of Q-wave, Ratio of
10 Amplitude of Q-wave to amplitude of R-wave, amplitude of R-wave, width of QT-
11 interval, width of QRS complex, width of PQ-interval, Standard deviation of the average
12 normal-to-normal R-R intervals;

13 analyzing said plurality of parameters and comparing said plurality of parameters
14 to a range in a set of a plurality of preset parameters;

15 determining whether a said user has an abnormal medical condition by
16 determining whether said plurality of parameters fall outside of said range in said set of
17 said plurality of preset parameters; and

18 determining whether to trigger an alarm warning the user of his or her medical
19 condition when said at least one of said plurality of parameters ~~fall~~ falls outside of said
20 ~~preset~~ ranges for said set of said plurality of preset parameters.

1 Claim 27 (original) The process as in claim 26, wherein said step of determining
2 whether a user has an abnormal condition includes determining at least one abnormal
3 condition selected from the group consisting of: sick sinus node syndrome, slow
4 ventricular rhythm, AV block II-III degree, paroxysm, tachycardia, sudden heart block,
5 sinus arrest, cardiac arrest, extrasystoles, group extrasystoles, paroxysm of
6 atrial/~~ventricular~~ ~~fibrillation-flutter~~ fibrillation/flutter, myocardial ischemia, myocardial
7 infarction, bundle branch blocks, ventricular tachyarrhythmia.

1 Claim 28 (currently amended): A process for analyzing a medical condition of a user
2 comprising the following steps:

3 reading at least one signal from the a user;
4 transferring said at least one signal into at least one digital signal;
5 extracting a plurality of parameters from said at least one digital signal;
6 analyzing said plurality of parameters and comparing said plurality of parameters
7 to a range in a set of a plurality of preset parameters;
8 predicting a possibility of a future occurrence of an abnormal medical condition
9 in the user using at least one of said plurality of parameters;
10 determining whether a user has an abnormal medical condition by determining
11 whether said plurality of parameters fall outside of said range in said set of said plurality
12 of parameters and determining whether to trigger an alarm warning the user of his or her
13 medical condition or possible future medical condition when said at least one of said
14 plurality of parameters ~~fall~~ falls outside of said ~~preset~~ ranges for said set of said plurality
15 of preset parameters.

1 Claims 29 (original): The process as in claim 28, wherein said abnormal medical
2 condition is a development of myocardial infarction or sudden cardiac death.

1 Claim 30 (currently amended) The process as in claim 28, wherein said step of predicting
2 a possibility of a future occurrence of an abnormal medical condition includes using at
3 least one of the following parameters: heart beats per minute of the user; ST init. which
4 is the ST segment level before observation of said user begins beginning, ST meas.
5 which is the ST segment level at the current ~~movement~~ moment, ST thresh. which is the
6 ST segment threshold at normal levels, QT meas. which is the QT interval duration at the
7 current moment; QT norm. which is the QT interval normal duration.

Claims 31-33 (canceled)

1 Claim 34 (currently amended): The process as in claim 28, further comprising the step
2 of setting a range for said at least one preset parameter to predict said future occurrence
3 of said abnormal medical condition.

1 Claim 35 (original): The process as in claim 28, further comprising the steps of inputting
2 the user's medical history into a database and storing said user's medical history.

1 Claim 36 (currently amended): The process as in claim 34, further comprising the step
2 of adjusting said range for said at least one preset parameter using at least one level of
3 adaptability.

1 Claim 37 (currently amended): The process as in claim 34, further comprising the step
2 of adjusting said range for said at least one preset parameter using a first level, a second
3 level and a third level of adaptability.

1 Claim 38 (original): The process as in claim 35, wherein said first level of adaptability
2 includes adjusting said range based upon at least one of the following user's
3 characteristics: age, gender, weight, or medical history.

1 Claim 39 (original): The process as in claim 37, wherein said second level includes
2 adjusting said range based upon a log file of cardiac events wherein said adjustment is
3 actuated by a person controlling the setting of the range.

1 Claim 40 (original): The process as in claim 37, wherein said third level includes
2 automatically adjusting said range.

1 Claim 41 (currently amended) An article of manufacture comprising:

2 a) a computer usable medium having a machine-readable program code means
3 for reading at least one signal from a user;

4 b) a machine-readable program code means for transferring said at least one
5 signal into at least one digital signal;

6 c) a machine-readable program code means for extracting a plurality of
7 parameters from said at least one digital signal;

8 d) a machine-readable program code means for analyzing said plurality of
9 parameters and comparing said plurality of parameters to a range in a set of a plurality
10 of preset parameters;

11 e) a machine-readable program code means for predicting a possibility of a future
12 occurrence of an abnormal medical condition in the user using at least one of said
13 plurality of parameters;

14 f) a machine readable program code means for determining whether a user has
15 an abnormal medical condition by determining whether said plurality of parameters fall
16 outside of said range in said set of said plurality of preset parameters; and

17 g) a machine readable program code means for determining whether to trigger an
18 alarm warning the user of his or her medical condition or a possible future medical
19 condition when said at least one of said plurality of parameters ~~fall~~ falls outside of said
20 ~~preset~~ ranges for said set of said plurality of preset parameters.

Claims 42-52 (canceled)

1 Claim 53 (New) A process for extracting and analyzing cardiac parameters of a user
2 comprising the following steps:

- 3 a) reading at least one signal of electrical activity of the heart from the user;
- 4 b) transforming said at least one signal into at least one digital signal;
- 5 c) extracting a plurality of cardiac parameters from said at least one digital
6 signal; and
- 7 d) predicting a possibility of a future occurrence of significant cardiac events
8 in the user using at least one of said plurality of cardiac parameters.

1 Claim 54 (New) The process as in claim 53, wherein said step of extracting the plurality
2 of cardiac parameters comprises the following steps:

- 3 determining characteristic points where said digital signal reaches maximums,
4 minimums or changes direction;
- 5 analyzing noise level in said digital signal;
- 6 determining the plurality of pulsometric parameters;
- 7 determining the plurality of QRS-complex parameters; and
- 8 averaging the plurality of pulsometric and QRS-complex parameters for a number
9 of significant R-R intervals.

1 Claim 55 (New) The process as in claim 54, wherein said step of determining
2 characteristic points includes:

- 3 extracting at least two pairs of consecutive significant dominant characteristic
4 points of maximum signal wherein said first pair is R_{i-1} , R_i and said second pair is R_i ,
5 R_{i+1} ;
- 6 determining at least two significant R-R intervals wherein said first R-R interval
7 is $R_{i-1}R_i$, and said second R-R interval is R_iR_{i+1} ;
- 8 determining at least one QRS-fragment comprised of two consecutive significant
9 R-R intervals;

10 determining at least one QRS-complex;
 11 extracting dominant characteristic points P, Q, J, S, and T in ~~QRS-complex~~ QRS-
 12 fragment; and
 13 extracting auxiliary characteristic points I, K, P1, P2, T1, and T2 in QRS-
 14 fragment.

1 Claim 56 (New) The process as in claim 54, wherein said step of analyzing noise level
 2 includes:
 3 calculating the noise level N for current R-R interval;
 4 comparing the noise level with a threshold value; and
 5 excluding current R-R interval if noise level exceeds threshold value.

1 Claim 57 (New) The process as in claim 56, wherein said step of calculation of the
 2 noise level N for current R-R interval includes using the following formula:
 3 believing $N=0$, then:
 4 for each given point j from interval $[R_{i-2}+e_1, R_i-e_1]$:
 5 if $|(V_j-V_{j-1})|>2^m$ and $|(V_j-V_{j+1})|>2^m$,
 6 then $N=N+2^m$, $m=5, \dots, j \in [R_{i-2}+e_1, R_i-e_1]$
 7 for each given point j from interval $[R_{i-2}+e_2, R_i-e_2]$:
 8 if $(V_j-V_{j-1})>2^m$ and $(V_j-V_{j+1})>2^m$,
 9 then $N=N+2^m$, $m=5 \dots, 2j \in [R_{i-2}+e_2, R_i-e_2]$
 10 wherein:
 11 e_1, e_2 —indentations from threshold points (threshold point are empiric
 12 values equal 75 ms and 115 ms respectively);
 13 V_j —amplitude in point j;
 14 N—noise level value.

1 Claim 58 (New) The process as in claim 54, wherein said step of determining the
 2 plurality of pulsometric parameters includes determining:

3 a heart rate;
4 a heart rate maximum;
5 a heart rate minimum;
6 a heart rate variability;
7 a number of single premature beats;
8 a number of groups of consecutive premature beats; and
9 an atrial/ventricular fibrillation/flutter.

1 Claim 59 (New) The process as in claim 54, wherein said step of determining a plurality
2 of QRS-complex parameters includes calculation of:
3 a ST-segment depression/elevation;
4 a width of a Q-wave (WQ);
5 an amplitude of the Q-wave;
6 a width of QRS-complex;
7 a width of PQ interval;
8 a width of QT interval;
9 an amplitude of R wave;
10 T wave inversion;
11 Ratio of amplitude of Q wave to amplitude of R wave; and
12 Standard Deviation of the average Normal-to-Normal R-R interval.

1 Claim 60 (New) The process as in claim 55, wherein said step of extracting R point
2 from said digital signal includes using the following formula:
3 the point R has been identified if:
4 $(V - V1) > A1$
5 $(V - V2) > A2$
6 wherein V is the amplitude at a current point along the QRS fragment;
7 V1 is the amplitude at (t-d1)

8 V2 is the amplitude at point (t-d2)
 9 wherein t is the current time and d1, d2, A1, and A2 are empiric
 10 constants.

1 Claim 61 (New) The process as in claim 55, wherein said step of extracting dominant
 2 characteristic point Q includes using the following formula:

3 the point Q has been identified if:
 4 $(d1/d2) \geq Q_r$ and $(A_r - A_i) > A_{rQ}$
 5 wherein $d1 = A_i - A_{i-3}$, $d2 = A_{i+3} - A_i$, and Q_r , A_{rQ} , and D_Q are empiric constants.

1 Claim 62 (New) The process as in claim 55, wherein said step of extracting dominant
 2 characteristic point S includes using the following formula:

3 the point S has been identified if:
 4 $A_{i+1} > A_1$ and $(A_R - A_i) > A_{RS}$ wherein $i = R, \dots, R + D_S$
 5 or
 6 $(A_i - A_{i-3}) < A_d$ and $(A_R - A_i) > A_{RQ}$, $i = R, \dots, R - D_S$
 7 or
 8 $(d1/d2) \geq S_r$ and $(A_r - A_i) > A_{RS}$
 9 wherein A_i is the amplitude, $d1 = A_i - A_{i-3}$, $d2 = A_{i+3} - A_i$, A_{RS} , A_d , D_S , S_r , and A_{RQ} are
 10 empiric constants.

1 Claim 63 (New) The process as in claim 55, wherein said step of extracting dominant
 2 characteristic point J includes using the following formula:

3 the point J has been identified if:
 4 $(A_{i-3} - A_i) < A_d$ $i = S, \dots, S + D_j$,
 5 wherein A_i - amplitude, A_d and D_j are empiric constants.

1 Claim 64 (New) The process as in claim 55, wherein said step of extracting dominant
 2 characteristic point T includes using the following formula:

3 the point T has been identified if the distance from point (i, A_i) to line (I,
 4 I_N)>T_{Amin},
 5 wherein (i, A_i) = maximum point and T_{Amin}=A_N for normal T-wave and
 6 T_{Amin}=A_{IN} for inverse T-wave;
 7 for flat T-wave
 8 (A_i-A_{i+5})> A_d, i=J, . . . , N2,
 9 wherein A_i = amplitude and A_N, A_{IN}, and A_d are empiric constants.

1 Claim 65 (New) The process as in claim 55, wherein said step of extracting dominant
 2 characteristic point P includes using the following formula:
 3 the point P has been identified if:
 4 A_i-A_{i-5}>A_d and A_i-A_{i+5}>A_d;
 5 wherein A_d is an empiric constant.

1 Claim 66 (New) The process as in claim 55, wherein said step of extracting auxiliary
 2 characteristic point I includes using the following formula:
 3 the point I has been identified if
 4 (A_{i-3}-A_i)< A_d and I = Q, . . . , Q-D_r
 5 wherein A_i = amplitude and A_d and D_r are empiric constants; and
 6 wherein the point I is considered equal to point Q if (A_{i-3}-A_i)≥ A_d.

1 Claim 67 (New) The process as in claim 55, wherein said step of extracting auxiliary
 2 characteristic point K includes using the following formula:
 3 the point K has been identified as (J+D_j, A_{j+D_j})
 4 wherein A_{j+D_j} is amplitude in point J + D_j and D_j is ~~an empiric~~ a preset constant.

1 Claim 68 (New) The process as in claim 55, wherein said step of extracting auxiliary
 2 characteristic points T1, T2, and P2 includes using the following formula:

the point is identified if the angle formed by the local isoline and the line between A_i and the point becomes less than the previous angle contained by the local isoline and the line between A_{i-1} and the point, and this tendency continues within a 40 ms time period.

Claim 69 (New) The process as in claim 55, wherein said step of extracting auxiliary characteristic point P1 includes using the following formula:

$$P1 = P - (P2 - P).$$

Claim 70 (New) The process as in claim 58, wherein said step of determining said atrial fibrillation flutter F includes using the following formulae:

$F = (F1 + F2) / X\%$ wherein F1 is ~~an extrasystole~~ a premature beat component, F2 is a variability component and X is an empiric constant;

$F1 = (E/G) * 100$ wherein E is the number of ~~extrasystoles~~ premature beats within G number of previous R-R intervals;

wherein if $F1 > 50\%$, then F1 is considered equal 50%;

$$FRR = (RR_{\max} - RR_{\min}) / RR_{\max} * 100;$$

wherein if $m1 > 2$ then $F2 = S2 / m1$ wherein,

S1 is the sum of all of the variability of the G intervals; or

wherein if $m2 > 2$ then S2 is the sum of all of the variability of all G intervals;

wherein if $m1 \leq 2$ AND $m2 \leq$ then $F2 = 0$; and

wherein M1 is the number of R-R intervals with variability $10\% < F_{RR} < 30\%$ and m2 is the number of R-R intervals with variability $F_{RR} < 10\%$.

Claim 71 (New) The process as in claim 53, wherein said step of predicting a possibility of a future occurrence of significant cardiac events in the user using at least one of said plurality of cardiac parameters includes using the following formula:

$$RR = 1 + \sqrt{K_1 * \left| \frac{ST_{meas} - ST_{init}}{ST_{init} + ST_{thresh}} \right|^2 + \left| \frac{QT_{meas.}}{QT_{norm.}} - 1 \right|^2 + \left| \frac{N_1 + K_2 * N_2 + K_3 * N_3}{HR} \right|^2}$$

4

5

wherein:

6

RR is the complex Relative Risk of sudden cardiac death and development of myocardial infarction;

8

HR is the heart rate;

9

ST init. = the initial value of ST-segment depression/elevation;

10

ST meas. = measured value ST-segment depression/elevation;

11

ST thresh. = threshold value of ST-segment depression/elevation;

12

QT meas.= measured value of QT interval;

13

QT norm. = normal value of QT interval calculated using Bazett's formula:

14

$$QT_{norm} = k * \sqrt{60 / HR}$$

15

k is a constant coefficient of .4 for males and .37 for females;

16

N1 is the number of single ventricular premature beats per min;

17

N2 is the number of groups of ventricular premature beats per min;

18

N3 is the number of ventricular fibrillation/flutter episodes per min.

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Claim 72 (New) The process as in claim 71, further comprising the step of adjusting constants K₁, K₂ and K₃ depending upon a set of clinical data obtained by predicting said abnormal medical condition, so that as more experiments and trials are performed, said constants may be modified to provide more accurate forecasting.

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Claim 73 (New) The process as in claim 72, wherein initial values of said constant K₁ is approximately 1.49, K₂ is approximately 34.91, and K₃ is approximately 73.68.

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